IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN

DAVID CHRISTENSON and ANNIKEN PROSSER *Plaintiffs,* v. ALEX AZAR II, in his official capacity as the Secretary of the Department of Health and Human Services. *Defendant.*	Case No. 20-cv-194 PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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Pursuant to FED.R.CIV.P. 56, Plaintiffs David Christenson and Anniken Prosser (collectively, "Plaintiffs") respectfully file this motion for summary judgment that the Secretary is barred by collateral estoppel from denying Mr. Christenson' and Mrs. Prosser's claims for Medicare coverage, as a matter of law, and that the coverage denials at issue in this case should be reversed.

This is an administrative review case, the resolution of which turns solely on an issue of law. As detailed in the Complaint and below, Mr. Christenson and Mrs. Prosser are suffering from a particularly lethal form of brain cancer (glioblastoma multiforme (GBM)). Even with the tumor treatment field therapy (TTFT) that is the subject of the coverage dispute, the two-year survival rate remains well below 50%.

Mr. Christenson and Mrs. Prosser have repeatedly litigated the issue of whether TTFT is a covered Medicare benefit for them (as well as the sub-issues of, e.g., whether TTFT is "medically reasonable and necessary"/"safe and effective"/not "experimental or investigational"). Both Mr. Christenson and Mrs. Prosser have prior decisions from ALJs finding in their favor on these issues. The Secretary did not appeal those decisions and they have now become final. Nevertheless, the Secretary continues to force Mr. Christenson and Mrs. Prosser to re-litigate the identical issues during the time they should be spending with family and focusing on their recovery.

This has to stop.

I LEGAL BACKGROUND

Collateral estoppel (*i.e.*, "issue preclusion") is a venerable common law doctrine that bars re-litigation of a legal or fact issue determined in a prior proceeding. Under the doctrine of collateral estoppel, "once an issue is actually and necessarily determined by a court of competent

jurisdiction, that determination is conclusive in subsequent suits based on a different cause of action involving a party to the prior litigation." *Montana v. United States*, 440 U.S. 147, 153-54 (1979).

In the Seventh Circuit, collateral estoppel applies if: 1) the issue sought to be precluded is the same as that involved in a prior litigation; 2) the issue was actually litigated; 3) the determination of the issue was essential to the final judgment; and 4) the party against whom estoppel is invoked was fully represented in the prior action. *See, e.g., C & N Corp. v. Kane*, 953 F.Supp.2d 903, 912 (E.D. Wisc. 2013) (Griesbach, J.) (*citing Matrix IV, Inc. v. Am. Nat'l Bank & Trust Co.*, 649 F.3d 539, 547 (7th Cir. 2011)).

Parallel/concurrent litigation is common. Where there is parallel/concurrent litigation, whichever case reaches finality first may have preclusive effect on the other. *See, e.g., Kline v. Burke Const. Co.*, 260 U.S. 226, 230 (1922); *Adkins v. Nestle Purina Petcare Co.*, 779 F.3d 481, 484 (7th Cir. 2015) ("The first to reach final decision can affect the other … through rules of claim and issue preclusion (res judicata and collateral estoppel)[.]"). In other words, a later-filed or decided case that reaches finality first may have preclusive effect on an earlier-filed, but still on-going litigation.

Because of the unique posture of the United States as a litigant, the Supreme Court has held that offensive, non-mutual collateral estoppel does not apply against the United States. *See U.S. v. Mendoza*, 464 U.S. 154 (1984). As a result, only a party to a prior proceeding with the government can assert collateral estoppel against the government. Here, Mr. Christenson and Mrs. Prosser are not seeking to collaterally estop the Secretary with respect to coverage for TTFT claims filed by any person other than themselves. Instead, Mr. Christenson and Mrs.

Prosser only contend that they should not have to re-litigate the same coverage issues against the Secretary that have already been finally and conclusively determined in their favor.

Proceedings giving rise to collateral estoppel are not limited to cases before federal or state courts. In *Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991), the Supreme Court held:

> We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

(internal citations omitted). *See also B & B Hardware, Inc. v. Hargis Industries, Inc.*, 135 S.Ct. 1293, 1302-3 (2015) (confirming that administrative decisions can be a basis for issue preclusion).

Collateral estoppel may be applied when an agency is acting in a judicial capacity and resolves issues properly before it and the procedures utilized by the agency do not prevent the party against whom estoppel will be applied from having a fair opportunity to present it case. *See, e.g., EZ Loader Boat Trailers, Inc. v. Cox Trailers, Inc.*, 746 F.2d 375, 377-78 (7th Cir. 1984). Stated somewhat differently, collateral estoppel effect can be given to a prior agency determination if: 1) the original action was properly before the agency; 2) the same disputed issues of fact are before the court as were before the agency; 3) the agency acted in a judicial

capacity; and 4) the parties had an adequate opportunity to litigate the issue before the agency. *See Meyer v. Rigdon*, 36 F.3d 1375, 1379-80 (7th Cir. 1994).

The application of collateral estoppel based on agency determinations (even against agencies) has been affirmed in numerous cases. *See, e.g., Continental Can Co., U.S.A., v. Marshall*, 603 F.2d 590 (7th Cir. 1979) (DOL collaterally estopped by prior decisions of department); *Bowen v. United States*, 570 F.2d 1311, 1321-23 (7th Cir. 1978) (NTSB acting in judicial capacity in prior proceeding, plaintiff collaterally estopped); *C & N*, 953 F.Supp.2d at 912-14 (defendant collaterally estopped by prior TTAB proceeding); *Brewster v. Barnhart*, 145 Fed.App'x. 542 (6th Cir. 2005) (SSA ALJ collaterally estopped by prior ALJ' work determination); *Islam v. U.S. D.H.S.*, 136 F.Supp.3d 1088 (N.D. Cal. 2015) (D.H.S. collaterally estopped by prior immigration judge's determination).

II FACTUAL BACKGROUND

A. Tumor Treatment Field Therapy (TTFT)

Glioblastoma multiforme (GBM) is an unusually deadly type of brain cancer. Without treatment, survival is typically 3 months. With earlier forms of treatment before TTFT, the survival rate at two years after treatment is ~31%, while at five years, only ~5% of patients are living. Individuals with recurrent GBM have a life expectancy of six months.[1]

More recently, treating GBM using alternating electric fields has been developed. This is known as tumor treatment field therapy (TTFT). Alternating electric fields interfere with tumor cell replication and have been shown to dramatically increase the period during which the GBM does not progress, as well as overall survival rates. Indeed, TTFT has proven so effective that, in

[1] "Recurrent" GBM means that the tumor has increased by 25% since the last treatment.

late 2014, a randomized clinical trial of TTFT was suspended because it would have been unethical to withhold TTFT treatment from the control group.[2]

In ground-breaking papers published in the Journal of the American Medical Association (JAMA)[3] in 2015 and 2017, TTFT was shown to increase the 2-year survival rate by more than 38% and to nearly triple the five-year survival rate.[4]

As reported, TTFT was the first significant advance in treating GBM in more than a decade. TTFT has become the standard of care for treating GBM and essentially all major private insurers cover TTFT. TTFT extends GBM patients' lives, in some cases, by years. Between January 2016 and December 2018, at least 93 scientific papers were published demonstrating the effectiveness of TTFT. It has a Level One recommendation in the National Comprehensive Cancer Network (NCCN) guidelines, *i.e.*, there is consensus, among the experts,

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[2] In much scientific research, study participants are randomly assigned to "control" and "test" groups. The "control" group does not receive the treatment being tested. In contrast, the "test" group does. Proceeding in this way facilitates the determination of which effects, if any, are the result of the tested treatment as opposed to normal variation among the study participants. During the course of a study, interim results are frequently measured to determine whether the study is proceeding as planned and whether any changes are needed. When the interim results indicate that the tested treatment has a significant effect on health or safety, either negative or positive, ethical guidelines dictate that the study should be halted. Thus, if the interim results indicate that the tested treatment was significantly more likely to result in death than the control group, the study would be halted and the treatment no longer given to the "test" group. Likewise, if the interim result indicated that the tested treatment was life-saving, the study would be halted and the treatment would be made available to the "control" group. In those circumstances, withholding the treatment from the "control" group would be unethical.

[3] The Journal of the American Medical Association (JAMA) is widely regarded as one of the most prestigious medical journals in the United States and the world.

[4] *See Stupp, et al.*, "MAINTENANCE THERAPY WITH TUMOR-TREATING FIELDS PLUS TEMOZOLOMIDE VS. TEMOZOLOMIDE ALONE FOR GLIOBLASTOMA: A RANDOMIZED CLINICAL TRIAL", JAMA, Vol. 314, No. 23, pgs. 2535-43 (December 15, 2015); *Stupp, et al.*, "EFFECT OF TUMOR TREATING FIELDS PLUS MAINTENANCE TEMOZOLOMIDE VS. MAINTENANCE TEMOZOLOMIDE ALONE ON SURVIVAL IN PATIENTS WITH GLIOBLASTOMA", JAMA, Vol. 318, No. 23, pgs. 2306-2316 (December 19, 2017).

based on a high level of evidence, that TTFT is a recommended intervention.[5] Further, TTFT is FDA approved.

The sole supplier of the equipment that delivers TTFT is Novocure, Inc. which manufactures the Optune system. The Optune system is rented on a monthly basis. Once a Medicare patient suffering from GBM is prescribed the Optune system, they will have monthly claims for Medicare coverage. Sadly, there is no known cure for GBM and patients prescribed TTFT treatment will have to continue that treatment for the rest of their lives.

B. The Medicare Appeals Process

People suffering from GBM and being treated with TTFT will have multiple claims for Medicare coverage. Typically, these claims will be submitted every one to three months to reflect their continued usage of the TTFT device. Each claim for Medicare coverage concerns only the one to three months at issue for that claim.

Claims submitted by beneficiaries enrolled in Original Medicare are subject to a five (5) level appeal process that can (and typically does) take more than a year. At issue at each stage of the process is whether the claim is a Medicare covered benefit/is medically reasonable and necessary for the beneficiary. The beneficiary begins by submitting a claim. *See* 42 C.F.R. §§ 405.920-928.[6] If the claim is denied, the beneficiary can request "redetermination." *See* 42 C.F.R. §§ 405.940-958. If the claim is still denied, the beneficiary can request "reconsideration." *See* 42 C.F.R. §§ 405.960-978.

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[5] This is the highest recommendation given to less than 10% of cancer treatments.

[6] At issue in this case are claims submitted under "Original Medicare" (*i.e.*, "Medicare Part B"). Accordingly, the regulatory citations herein are those applicable to Part B claims. Medicare Part C (*i.e.*, "Medicare Advantage Plans") is governed by similar/identical regulations. *See* 42 C.F.R. §§ 422.560-626.

If the claim is still denied, the Secretary is required to provide "hearings" for appeals to the "same extent" as is provided for in Social Security hearings. *See* 42 U.S.C. § 1395ff(b)(1)(A) (*citing* 42 U.S.C. § 405(b)). That is, in conducting the hearings, the Secretary is authorized to administer oaths, examine witnesses, and receive evidence.

The Secretary has promulgated regulations concerning the conduct of the "hearing" by administrative law judges (ALJs). *See* 42 C.F.R. §§ 405.1000-1058. At a minimum, in the case where the beneficiary is represented by counsel, the hearings are adversarial. In such a case, the Secretary's representative (in the form of the Centers for Medicare and Medicaid Services (CMS) or a "contractor" to Medicare) has the opportunity to litigate as a party. *See* 42 C.F.R. §§ 405.1008 and 405.1010.

In that capacity, the Secretary (like the beneficiary) can submit evidence (42 C.F.R. § 405.1018), object to the timing of the hearing (42 C.F.R. § 405.1020), object to the issues before the ALJ (42 C.F.R. § 405.1024); object to the assigned ALJ (42 C.F.R. § 405.1026); present evidence in the form of documents and witnesses (including through subpoenas), cross-examine witnesses, and present and argument (42 C.F.R. § 405.1036); and take discovery (42 C.F.R. § 405.1037). After the hearing, the ALJ issues a written decision that includes findings of fact, conclusions of law, and the reasons for the decision and must be based on the evidence admitted at the hearing. *See* 42 C.F.R. § 405.1046.

Like the beneficiary, if the Secretary is dissatisfied with the decision of the ALJ, the Secretary can appeal to the Medicare Appeals Council ("Council"). *See* 42 C.F.R. §§ 405.1100-1140. Indeed, regardless of whether the Secretary chooses to participate in the hearing, the Secretary can appeal an ALJ's decision on so-called "own motion" review. *See* 42 C.F.R. § 405.1110.

Finally, if the beneficiary is dissatisfied with a decision from the Council, they can seek judicial review. *See* 42 U.S.C. § 1395ff(b)(1)(A) (*citing* 42 U.S.C. § 405(g)).

Although the statues and regulations require both ALJs and the Council to issue decisions within 90 days, those deadlines are routinely missed. *See, e.g.,* 42 U.S.C. § 1395ff(d)(2). Thus, Medicare beneficiaries seeking coverage are often thrown into a multi-year effort to obtain coverage or at least get a decision on each denied claim before they can seek relief in a federal court.

C. Mr. Christenson

David Christenson is a 66-year old husband of 43 years to wife Barbara, father of two, and grandfather to two. Prior to his retirement, Mr. Christenson was a software developer with Kimberly Clark. After his retirement, Mr. Christenson kept busy by driving disabled veterans to medical appointments. In addition to spending time with his family, Mr. Christenson is an avid bicycle rider and sports fan - supporting the UW Badgers and Milwaukee Bucks. After his diagnosis with GBM in July 2015, and surgery and chemo-radiation, Mrs. Christenson was prescribed the Optune TTFT device.

1. ALJ Tyler' April 2, 2019 Decision Granting Coverage:

Mr. Christenson sought Medicare coverage for his TTFT device for the months of January-April 2018 and his claim was denied initially, denied on redetermination, and denied on reconsideration. Thereafter, on February 5, 2019, through his counsel Parrish Law Offices, Mr. Christenson requested an ALJ hearing and subsequently submitted a pre-hearing brief. *See* Exhibit A.

When neither CMS nor a contractor elected to appear, pursuant to 42 C.F.R. § 405.1000(g), on April 2, 2019, ALJ Thomas Tyler issued an on-the-record decision favorable to

Mr. Christenson in ALJ Appeal No. 1-8285652321. Copy attached as Exhibit B. Among a number of findings supporting TTFT coverage, Judge Tyler found:

1) "The results of these studies determined that Optune in combination with temozolomide was an effective treatment of this particular brain cancer, whether newly diagnosed or recurrent, that resulted in significant improvement in life expectancy of most patients." (Decision at 7);

2) "The FDA approval of Optune, the overwhelming medical research evidence and the medical notes of [Mr. Christenson's] physician disclosed that Optune is effective in extending the lives of patients who have been newly diagnosed or have recurrent glioblastoma." (Decision at 7);

3) "Consequently, the undersigned finds that the Medicare requirements have been met. Accordingly, the ALJ finds that the TTFT treatment provided to [Mr. Christenson] in this case are covered under Medicare Part B." (Decision at 7); and

4) "Based on the foregoing, the undersigned concludes as a matter of law that the Optune Tumor Treatment Field Therapy services were shown to be medically reasonable and necessary and are covered under Medicare. [Mr. Christenson] is entitled to reimbursement of the costs billed." (Decision at 7).

The Secretary did not appeal Judge Tyler's decision and it has become final.

2. ALJ Zettel' June 26, 2019 Decision Granting Coverage:

Mr. Christenson sought Medicare coverage for his TTFT device for the months of May-October 2018 and his claims were denied initially, denied on redetermination, and denied on reconsideration. Thereafter, on March 29, 2019, through his counsel Parrish Law Offices, Mr. Christenson requested an ALJ hearing and subsequently submitted a pre-hearing brief. *See* Exhibit C.

On May 15, 2019, ALJ Richard Zettel held a hearing at which neither CMS nor a contractor appeared but Mr. Christenson's representative (Debra Parrish) did. Thereafter, on June 26, 2019, ALJ Zettel issued a decision favorable to Mr. Christenson in ALJ Appeal Nos. 1-8416270832 and 1-8416229632. Copy attached as Exhibit D. Among a number of findings supporting TTFT coverage, Judge Zettel found:

1) "The record and the hearing testimony support that TTFT is a safe and effective treatment of glioblastoma." (Decision at 7);

2) "Therefore, the ALJ … concludes that TTFT is a safe and effective treatment of recurrent glioblastoma." (Decision at 7);

3) "Ms. Miles state that [Mr. Christenson] was diagnose[d] with brain cancer in July 2015 and was put on Optune. Ms. Miles said that [Mr. Christenson] was still alive, which is phenomenal." (Decision at 7);

4) "… [T]he TTFT provided to [Mr. Christenson] on the dates of service was medically reasonable and necessary. The TTFT provided to [Mr. Christenson] from May 3, 2018, through October 3, 2018, is reimbursable under Part B of Medicare." (Decision at 7); and

5) "The ALJ concludes that the TTFT provided to [Mr. Christenson] on multiple dates of service was medically reasonable and necessary. Accordingly, the ALJ finds that the TTFT provided to [Mr. Christenson] from May 3, 2018, through October 3, 2018, is reimbursable under Part B of Title XVIII of the Act." (Decision at 7-8).

The Secretary did not appeal Judge Zettel's decision and it has become final.

3. ALJ Watson' September 12, 2019 Decision Denying Coverage:

Mr. Christenson sought Medicare coverage for TTFT for the months of November 2018-January 2019 and his claims were denied initially, denied on redetermination, and denied on reconsideration. Thereafter, on March 29, 2019, through his counsel Parrish Law Offices, Mr. Christenson requested an ALJ hearing and subsequently submitted a pre-hearing brief. *See* Exhibit E.

On August 28, 2019, ALJ Scott Watson held a hearing in Appeal No. 108630709341. While Mr. Christenson was represented by his counsel, Debra Parrish, neither CMS nor a contractor appeared. Thereafter, on September 12, 2019, ALJ Watson issued a decision denying coverage. Copy attached as Exhibit F. Contrary to the prior decisions, ALJ Watson found:

1) "For the reasons set forth below, I agree with the previous denial and conclude that Medicare Part B does not provide for coverage of TTFT for the treatment of [Mr. Christenson's] recurrent GBM." (Decision at 4);

2) "I … find that TTFT for the treatment of recurrent GBM is considered not reasonable and necessary." (Decision at 4);

3) "… I find that [Mr. Christenson] is not entitled to coverage of the Optune tumor treatment field therapy (E0766) received on November 13, 2018, December 3, 2018, and January 3, 2019.") (Decision at 5); and

4) "Medicare Part B does not cover the tumor treatment field therapy (E0766) for recurrent GBM, therefore, [Mr. Christenson] is not entitled to coverage of the TTFT (E0766) provided to [Mr. Christenson] on November 13, 2018, December 3, 2018, and January 3, 2019." (Decision at 5).

Mr. Christenson timely appealed and, *inter alia*, brought the two prior favorable decisions to the Council's attention and argued collateral estoppel. Pursuant to 42 U.S.C. § 1395ff(d)(2), the Council was required to issue a ruling within 90 days. When no decision was received by that date, Mr. Christenson requested "escalation" pursuant to 42 C.F.R. § 405.1132 again bringing the prior favorable decisions as well as authority on collateral estoppel from the Supreme Court to the Council's attention. Copy attached as Exhibit G. Subsequently, the Council did not issue a decision which authorized the filing of this suit in district court.

D. Mrs. Prosser

Anniken Prosser is a 36-year old mother to six-year old son Liam, wife of nearly 10 years to husband Barry, and a Medicare beneficiary. A Wisconsin native, Mrs. Prosser enjoys drawing, writing lyrics for and singing in several musical groups, and spending time with her family. Mrs. Prosser was diagnosed with GBM in February 2016. After surgery and chemo-radiation, Mrs. Prosser was prescribed the Optune TTFT device in June 2016.

1. ALJ Woodyard' May 20, 2019 Decision Granting Coverage:

Mrs. Prosser sought Medicare coverage for her TTFT device for the months of August-October 2018 and her claim was denied initially, denied on redetermination, and denied on reconsideration. Thereafter, on March 27, 2019, through her counsel Parrish Law Offices, Mrs.

Prosser requested an ALJ hearing and subsequently submitted a pre-hearing brief. *See* Exhibit H.

When neither CMS nor a contractor responded to the Notice of Hearing, pursuant to 42 C.F.R. § 405.1000(g), on May 20, 2019, ALJ Kimberley Woodyard issued an on-the-record decision favorable to Mrs. Prosser in ALJ Appeal No. 1-8416188648. Copy attached as Exhibit I.[7] Among a number of findings supporting TTFT coverage, Judge Woodyard found:

1) "TTFT has been shown to be safe and effective for use in patients with recurrent and newly diagnosed glioblastoma, and it is medically reasonable and necessary to treat Ms. Prosser's condition." (Decision at 7);

2) "On October 5, 2015, the FDA gave premarket approval for the use of Optune in patients with newly diagnosed glioblastoma." (Decision at 8);

3) "From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence." (Decision at 8);

4) "The FDA approval, along with the other evidence below, support the conclusion that the device is safe, and not experimental or investigational." (Decision at 8);

5) "These trials show that the Optune device is appropriate for treatment of Ms. Prosser's glioblastoma." (Decision at 8);

6) "… Optune (TTFT) has been shown to be safe and effective and is not experimental. Medicare coverage is thus available for the tumor treatment field therapy." (Decision at 9); and

7) "Medicare coverage exists for the Optune Tumor Treatment Field Therapy services (E0766) provided to [Mrs. Prosser] …" (Decision at 9).

The Secretary did not appeal Judge Woodyard's decision and it has become final.

2. ALJ Figueroa' June 27, 2019 Decision Granting Coverage:

Mrs. Prosser sought Medicare coverage for her TTFT device for the months of May-July 2018 and her claim was denied initially, denied on redetermination, and denied on

[7] *Id* at 4 ("As of the date of this decision, no contractor has responded to the Notice of Hearing.").

reconsideration. Thereafter, on March 19, 2019, through her counsel Parrish Law Offices, Mrs. Prosser requested an ALJ hearing and subsequently submitted a pre-hearing brief. *See* Exhibit J.

On May 28, 2019, ALJ Lissette Figueroa held a hearing in Appeal No. 1-8380637906. While Ms. Prosser was represented by her counsel, Bridget Noonan of the Parrish Law Offices, neither CMS nor a contractor chose to appear. Thereafter, on June 27, 2019, ALJ Figueroa issued a decision favorable to Mrs. Prosser. Copy attached as Exhibit K. Among a number of findings supporting TTFT coverage, Judge Figueroa found:

1) "For the reasons set forth below, I find that the tumor treatment field therapy administered to the appellant on the dates of service at issue was medically reasonable and necessary." (Decision at 9);

2) "This trial show that the Optune device was safe, non-investigational and effective. Moreover, this trial show that the Optune devices was appropriate for this individual Enrollee's needs, specifically the treatment of newly discovery glioblastoma." (Decision at 12);

3) "Additional material submitted by [Mrs. Prosser] also shows the medical community generally accepts the use of TTFT." (Decision at 13);

4) "… I … find that the Optune device will be considered reasonable and necessary as specifically applied to [Mrs. Prosser's] diagnosis and treatment regimen." (Decision at 13);

5) "Therefore, the record supports the claimed Optune device treatment was safe and effective and clinically appropriate. Accordingly, the device is reasonable and necessary for the treatment of [Mrs. Prosser's] glioblastoma." (Decision at 14); and

6) "[Mrs. Prosser's] use of the Optune device, HCPCs Code E0766, during the dates of service meets requirement for Medicare Part B DME coverage because the device is shown to: meet the definition of durable medical equipment, to have been reasonable and necessary for the treatment of [Mrs. Prosser's] GBM, and to have been for us in]Mrs. Prosser's] home." (Decision at 15).

The Secretary did not appeal Judge Figueroa's decision and it has become final.

3. ALJ Sardinas' March 18, 2020 Decision Granting Coverage:

Mrs. Prosser sought Medicare coverage for her TTFT device for the months of May-August 2019 and her claim was denied initially, denied on redetermination, and denied on

reconsideration. Thereafter, on January 29, 2020, through her counsel Parrish Law Offices, Mrs. Prosser requested an ALJ hearing and subsequently submitted a pre-hearing brief. *See* Exhibit L.

When neither CMS nor a contractor appeared, pursuant to 42 C.F.R. § 405.1038(a), ALJ Adalberto Sardinas elected to issue a favorable, on-the-record decision in Appeal No. 3-9079666355 on March 18, 2020. Copy attached as Exhibit M. Among a number of findings supporting TTFT coverage, Judge Sardinas found:

1) "Optune, previously called NovoTTF-100A System, received FDA premarket approval for use in patient with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the Provider received premarket approval from the FDA for use of Optune in patients newly diagnosed with glioblastoma." (Decision at 7);

2) "By the time of its 2018 updates to these guidelines, the NCCN had increased its rating for alternating electric field therapy (used in conjunction with standard RT and concurrent temozolmide and adjuvant temozolomide) to category I, the NCCN's highest rating, meaning that '[b]ased upon high-level evidence there is uniform NCCN consensus that the intervention is appropriate.'". (Decision at 8);

3) "From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence. This also shows that the device is not experimental or investigational." (Decision at 8);

4) "Results from a phase III clinical trial utilizing TTFT in patients with newly diagnosed glioblastoma showed that the addition of TTFT to maintenance temozolomide chemotherapy 'significantly prolonged progression-free and overall survival." (Decision at 8);

5) "It provides convincing evidence that TTFT treatment is accepted in the medical community as not experimental or investigational." (Decision at 9);

6) "I find that [Mrs. Prosser] has submitted ample evidence to support a favorable decision in this appeal based on the peer-reviewed literature, FDA approval, and overwhelming current acceptance in the medical community for the Optune system as a treatment option for recurrent and newly diagnosed glioblastoma." (Decision at 9);

7) "In this case, given the aggressive nature of the GBM tumor, it appears from all the literature that TTFT is [Mrs. Prosser's] most promising FDA approved treatment option available to her and that this treatment option has been widely accepted as the standard treatment in patients with recurrent and newly diagnosed GBM." (Decision at 9);

8) "… I find that TTFT through the Optune device is a covered treatment that is safe and effective based on the multiple peer-reviewed publications. TTFT was preoperly ordered by [Mrs. Prosser's] treating physician in accordance with accepted standards of medical practice for treatment of [Mrs. Prosser's] glioblastoma. For all of the foregoing reasons, I conclude that the TTFT device known as Optune has been shown to be safe and effective and is medically reasonable and necessary for the treatment of [Mrs. Prosser's] condition." (Decision at 9);

9) "Based on the foregoing, I find that [Mrs. Prosser] is entitled to Medicare payment for the services at issue." (Decision at 9); and

10) "It is my decision, based on applicable laws, regulations and CMS guidance, that [Mrs. Prosser] is entitled to Medicare payment for the Optune Tumor Treatment Field Therapy (Optune TTFT) billed as electrical stimulation device used for cancer treatment (E0766)[.]" (Decision at 10).

To date, the Secretary has not appealed Judge Sardinas' decision and it will become final on May 18, 2020. Plaintiffs include the decision here because, depending on whether the Secretary does appeal *before* May 18, 2020 and whether this Court issues a decision *after* May 18, 2020, Judge Sardinas' decision would be a final decision on which collateral estoppel may be based.

4. ALJ Grow' June 19, 2019 Decision Denying Coverage:

Mrs. Prosser sought Medicare coverage for her TTFT device for the months of January-April 2018 and her claim was denied initially, denied on redetermination, and denied on reconsideration. Thereafter, on January 29, 2020, through her counsel Parrish Law Offices, Mrs. Prosser requested an ALJ hearing and subsequently submitted a pre-hearing brief. *See* Exhibit N.

On May 20, 2019, ALJ J. Grow held a hearing in Appeal No. 1-8390277469. While Ms. Prosser was represented by her counsel, Debra Parrish, neither CMS nor a contractor chose to appear. Thereafter, on June 19, 2019, ALJ Grow issued a decision denying coverage. Copy attached as Exhibit O.

By contrast to the decisions of the other ALJs finding coverage, ALJ Grow held that he could not even consider the issue. This was so, Judge Grow held because the "compelling" evidence supporting coverage submitted by Mrs. Prosser amounted to a challenge to the reasons for denying coverage and, Judge Grow held, that was barred. Decision at 5 ("I cannot make those types of findings here because I do not have the record upon which the LCD is based before me."). Accordingly, Judge Grow held: "Medicare does not cover the item and services [Mrs. Prosser] received on the dates of service at issue." *Id.*

Mrs. Prosser timely appealed and, *inter alia*, brought the two prior favorable decisions to the Council's attention and argued collateral estoppel. Again, when no decision was received within 90 days, Mrs. Prosser requested escalation, and brought the prior favorable decisions to the Council's attentions as well as authority from the Supreme Court. Copy attached as Exhibit P. Subsequently, the Council did not issue a decision which authorized the filing of this suit in district court.

III DISCUSSION

As a result of the separate and final decisions finding TTFT to be a covered benefit/"medically reasonable and necessary" for Mr. Christenson and Mrs. Prosser, the Secretary should be collaterally estopped from issuing denials on the same grounds that were rejected by those other final decisions. Pursuant to 42 U.S.C. § 405(g) (fourth sentence), the Court should reverse the Secretary's denials, order coverage, and remand these cases with instructions to the Secretary to effectuate the Court's decision.

A. The Department Was Acting in a Judicial Capacity When It Issued the Prior Decisions

Out of an abundance of caution, Plaintiffs address the issue of whether the Department was acting in a "judicial capacity" when it issued the prior decisions and whether the procedures

adopted by the Secretary provided the Secretary with a fair opportunity to present his case. There can be little dispute on either point.

As an initial matter, pursuant to the statute, the Secretary is authorized to administer oaths, examine witnesses, and receive evidence in conducting the hearings. *See* 42 U.S.C. § 405(b). The Secretary has further issued regulations confirming the "judicial" and adversarial nature of the hearings and providing the Secretary a fair opportunity to present his case.

As detailed above, at a minimum when the beneficiary is represented, "hearings" before the Secretary are conducted by Administrative Law Judges and the Secretary (through his representatives) has an opportunity to submit evidence, object to the timing of the hearing, object to the issues at the hearing, object to the assigned ALJ, present evidence in the form of documents and witnesses (including through subpoenas), take discovery, cross-examine witnesses, and present argument. *See* 42 C.F.R. §§ 405.1018, 1020, 1024, 1026, 1036, and 1037. After the hearing, the ALJ issues a written decision including findings of fact and conclusions of law and the reasons for the decision. *See* 42 C.F.R. § 405.1046. Further, if the Secretary is dissatisfied with the ALJ's decision, the Secretary can appeal to the Council using the procedures of 42 C.F.R. §§ 405.1100-1140 (appeal as a party) or 42 C.F.R. § 405.1110 ("own motion review").

Thus, in making the prior decisions on which estoppel is based, the Secretary (through his administrative law judge) was acting in a judicial capacity and the Secretary had a fair opportunity to present his case.

As detailed above, the Secretary chose not to take advantage of these opportunities. That is of no moment because collateral estoppel is only concerned with whether the party against whom collateral estoppel is invoked had a fair opportunity to present their case, not whether they

chose to take advantage of that opportunity. *See, e.g., Meyer*, 36 F.3d at 1379-80; *EZ Loader*, 746 F.2d at 377-78. Further, it would make little sense to force Plaintiffs to repeatedly carry their burdens in the litigation as well as the burdens placed on the courts/judicial bodies, merely because the Secretary chose to make no effort in this regard. Such an approach would be contrary the very purposes of collateral estoppel.[8]

B. Collateral Estoppel

Collateral estoppel should conclusively bar the Secretary from re-litigating the issue of TTFT coverage for Mr. Christenson and Mrs. Prosser.

1. The Issue Sought to be Precluded is the Same as That Involved in the Prior Action

At issue in any Medicare coverage litigation is whether the device/service is a Medicare covered benefit for the beneficiary. This conclusion involves the sub-issues of whether the device/service is "medically reasonable and necessary" for the beneficiary and the further sub-issue of whether the device/service is "safe and effective."[9] *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A) (any item which is not "medically reasonable and necessary" is excluded from coverage). Thus, whenever a coverage decision has determined that a device/service is a Medicare covered benefit, it has necessarily determined that the device/service is medically reasonable and necessary for that particular beneficiary as well as that the device/service is "safe and effective."

[8] Simply as an example, because the Secretary has forced Plaintiffs to repeatedly litigate the issue of TTFT coverage, so far, Plaintiffs have been the subject of seven ALJ decisions on the exact same issue.

[9] Under Medicare's rules, it can never be "medically reasonable and necessary" to provide a device/service that is not "safe and effective."

In the present case, Plaintiffs seek to preclude the Secretary from continuing to litigate, dispute, or deny that TTFT is a Medicare-covered benefit (and the sub-issues of whether TTFT is "medically reasonable and necessary"/ "safe and effective") for Mr. Christenson and Mrs. Prosser.

As noted above, in one or more final decisions on separate claims brought by the same plaintiffs, the ALJ decided the exact same issue of whether TTFT was a Medicare covered benefit (and the sub-issues of whether it is "medically reasonable and necessary"/"safe and effective").

Mr. Christenson:

For Mr. Christenson, that issue was disputed and the subject of both Judge Tyler and Judge Zettel's final decisions. See Tyler Decision at 1 ("The issue is whether the tumor treatment field therapy (TTFT) provided to [Mr. Christenson] from January 3, 2018 to April 3, 2018 is covered under Medicare Part B."); 7 ("… the ALJ finds that the TTFT treatment provided to [Mr. Christenson] in this case are covered under Medicare Part B."); Zettel Decision at 2 ("The ALJ is asked to decide whether the TTFT provided to [Mr. Christenson] on multiple dates of service is reimbursable under Part B of [the Medicare Act.]"; 7-8 ("… the ALJ finds that the TTFT provided to [Mr. Christenson] … is reimbursable under Part B of Title XVIII of the Act."

That same issue was disputed and the subject to Judge Watson's decision denying coverage. Watson Decision at 5 ("Medicare Part B does not cover tumor treatment field therapy (E0766) for recurrent GBM, therefore [Mr. Christenson] is not entitled to coverage of the TTFT 9E0766) provided to [Mr. Christenson.]").

Likewise, the sub-issue of whether TTFT was "medically reasonable and necessary" for Mr. Christenson was the same in both the Tyler and Zettel decisions granting coverage as well as the Watson decision denying coverage. See Tyler Decision at 7 (TTFT was "shown to be medically reasonable and necessary and covered under Medicare."); Zettel Decision at 7 (TTFT "was medically reasonable and necessary"); Watson Decision at 4 (TTFT is "not reasonable and necessary.").

Mrs. Prosser:

For Mrs. Prosser, the issue of whether TTFT is a covered benefit was disputed and the subject of the decisions by Judges Woodyard, Figueroa, and Sardinas. See Woodyard Decision at 9 ("Medicare coverage is thus available for tumor treatment field therapy"); Figueroa Decision at 2 ("Is [Mrs. Prosser] entitled to Medicare reimbursement under Part B of [the Medicare Act] for tumor treatment field therapy[.]"; 15 ("[Mrs. Prosser's] use of the Optune device … meets requirements for Medicare Part B DME coverage[.]"; Sardinas Decision at a ("The issue to be decided is whether under the provisions of [the Medicare Act] and implementing regulations, Medicare reimbursement can be made for Optune TTFT[.]"; 9 (Mrs. Prosser "is entitled to Medicare payment for the services at issue.").

That same issue was disputed and the subject of Judge Grow's decision denying coverage. Grow Decision at 1 ("Issues: Whether Medicare cover the electrical stimulation device/treatment[.]"; 5 ("Medicare does not cover the item and services [Mrs. Prosser] received[.]"

Likewise, the sub-issue of whether TTFT is "medically reasonable and necessary" was also the same in the Woodyard', Figueroa', and Sardinas' decisions granting coverage and the Grow' decision denying coverage. See Woodyard Decision at 7 ("… it is medically reasonable

and necessary to treat Ms. Prosser's condition."); Figueroa Decision at 15 ("… reasonable and necessary to treat [Mrs. Prosser's] GBM."; Sardinas Decision at 9 ("… medically reasonable and necessary for the treatment of [Mrs. Prosser's] condition."; Grow Decision at 4 (an LCD provides: "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary."; 5 ("… I must substantially defer to the LCD and find no coverage.").

Thus, in all TTFT claims brought by Mr. Christenson and Mrs. Prosser, the same determinative issues were presented, and each Plaintiff has a final decision on those issues in his or her favor.

2. The Issue Was Actually Litigated in the Prior Proceedings

As detailed above, the issue of whether TTFT was a Medicare-covered benefit/was "medically reasonable and necessary" for each of the Plaintiffs was actually litigated in each of the prior favorable cases.

3. The Determination of the Issue Was Essential to the Final Judgment

Of course, the favorable ALJ decisions being invoked for collateral estoppel are final decisions by ALJs within the jurisdiction of the Secretary's Department itself. That the Secretary did not appeal the adverse ALJ judgments and the fact that they have become final is also beyond dispute. *See* 70 Fed.Reg. 36386-7 (June 23, 2005) ("The ALJs within the Office of Medicare Hearings and Appeals issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council[.]"); 42 C.F.R. § 405.1102 ("… a written request for a Council review within 60 calendar days …"). *See also Smith v. Berryhill*, 139 S.Ct. 1765, 1775-6 (2019) (under APA, action is "final" if it: 1) marks the consummation of the agency's decisionmaking process; and 2) is one by which rights have been determined or from which legal

consequences will flow). Thus, the third factor for collateral estoppel is fully established for each plaintiff.

Of course, the base issue being litigated is whether Medicare coverage exists for TTFT for Mr. Christenson and Ms. Prosser. Thus, the determination of that issue was essential to each of the prior judgments so finding.

Likewise, because there could be no determination that TTFT was a Medicare covered benefit for Mr. Christenson and Mrs. Prosser without a determination that TTFT was "medically reasonable and necessary" for them, that determination was essential to the final judgment. Likewise, because whether something is "medically reasonable and necessary" is itself dependent on whether it is "safe and effective", again, that finding was essential to the final judgment.

4. The Party Against Whom Estoppel is Invoked Was Fully Represented in the Prior Action

Here, there can be little doubt that the Secretary was fully represented in the prior actions. As detailed above, in each case, the Secretary (through his representatives) had an opportunity to appear and take advantage of the full panoply of rights as a litigant. Nevertheless, despite a bevy of lawyers representing the Secretary in numerous fora, the Secretary chose not to avail himself of that opportunity. Thus, the Secretary was fully represented in the prior action but elected not to appear.

5. Other Comments

The fact that, in some cases, the favorable ALJ decision giving rise to collateral estoppel occurred after the unfavorable ALJ decision at issue here is of no moment. For example, Mrs. Prosser asserts, in part, that the Secretary is estopped from making the coverage denial in ALJ

Grow's decision of June 19, 2019 by the decisions of ALJs Figueroa and Sardinas dated June 29, 2019 and March 18, 2020.[10]

As indicated, whichever decision reaches finality first may give rise to collateral estoppel against an earlier, but still on-going, litigation. *See Adkins*, 779 F.3d at 484. Once the Secretary elected to allow the favorable decisions of ALJs Figueroa and Sardinas (presumably) for Mrs. Prosser become final, he should be estopped from continuing to litigate that same issue in all pending and future claims by the same Plaintiffs.

Accordingly, the Secretary should be estopped from denying that TTFT is a Medicare covered benefit for Mr. Christenson and Mrs. Prosser (as well as the sub-issue of whether TTFT is "medically reasonable and necessary") to treat their GBM conditions.

C. The Decisions At Issue Should Be Reversed and Coverage Ordered

Once this Court properly applies collateral estoppel against the Secretary with respect to the issue of whether TTFT is a covered benefit/is "medically reasonable and necessary" for Plaintiffs, the decisions at issue should be reversed. Each of the decisions denying coverage was premised solely on the conclusion that TTFT was not "medically reasonable and necessary" for each of the Plaintiffs. That is, there was no other basis for the denial of coverage (*e.g.*, the beneficiary passed away). Thus, if the Secretary is collaterally estopped from re-litigating that issue, then there is no reason that coverage can/should be denied.

Pursuant to 42 U.S.C. § 405(g) (fourth sentence), this Court can modify or reverse the Secretary's decisions "with or without remanding the cause for a rehearing." If the Secretary is collaterally estopped from denying coverage to Plaintiffs in Appeal No. 1-8630709341 (for Mr.

[10] Again, dependent on whether the Secretary appeals ALJ Sardinas' decision before May 18, 2020 and whether this Court issues a decision after May 18, 2020.

Christenson) and Appeal No. 1-8390277469 (for Mrs. Prosser), then there is no need or reason for further review by the Secretary and coverage should be ordered.

III. CONCLUSION

The Secretary should be collaterally estopped from denying that TTFT is a covered Medicare benefit and "medically reasonable and necessary" for Mr. Christenson and Mrs. Prosser. Mr. Christenson and Mrs. Prosser have sustained their burden of proving coverage multiple times and should not be tormented by repeated litigation.

The decisions at issue in this case should be reversed and coverage of Mr. Christenson and Mrs. Prosser's claims ordered.

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Respectfully submitted,

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